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IN RE CARDIZEM AND VALLEY DRUG: A VIEW FROM THE FAULTLINE BETWEEN PATENT AND ANTITRUST IN PHARMACEUTICAL SETTLEMENTS

Richard D. Chaves Mosier & Steven W. Ritcheson†

I. INTRODUCTION

The line where the patent laws and antitrust laws meet has been described as an “accommodation,”¹ an “intersection,”² an “impact,”³ a “clash,”⁴ and, here, a faultline. This case note reveals that faultline within the context of two recent court decisions that analyze antitrust claims brought against parties to patent settlement agreements involving the Hatch-Waxman Act, 21 U.S.C. §§ 301–99. Specifically, we examine the seemingly contradictory decisions of the Sixth Circuit’s opinion in *In re: Cardizem CD Antitrust Litigation* and the Eleventh Circuit’s opinion in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*

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1. See *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 179–80 (1965) (Harlan, J., concurring).

2. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1307 (11th Cir. 2003).

3. See Thomas F. Cotter, Commentary, *Refining the “Presumptive Illegality” Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemly*, 87 MINN. L. REV. 1789, 1791 (2003).

4. See 35 U.S.C. § 154(a)(2); 10 PHILLIP E. AREEDA, HERBERT HOVENKAMP & EINER ELHAUGE, *ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION*, ¶ 1780a, at 471 (Little, Brown and Co. 1996) [hereinafter AREEDA, HOVENKAMP & ELHAUGE].

*In re: Cardizem CD Antitrust Litigation*⁵ pitted Hoechst Marion Roussel, Inc. ("HMR"), the producer of Cardizem CD—a highly profitable brand-name prescription drug used for treating angina and hypertension and preventing heart attacks and strokes—against Andrx Pharmaceuticals, Inc. ("Andrx"), a manufacturer of generic drugs. On June 13, 2003, the United States Court of Appeals for the Sixth Circuit ("Sixth Circuit") held an agreement entered into between HMR and Andrx as *per se* illegal under antitrust laws. The agreement provided that Andrx, in exchange for quarterly payments of \$10 million, would refrain from marketing any generic version of HMR's Cardizem CD even after Andrx had received Food and Drug Administration ("FDA") approval.⁶ In finding this agreement was a *per se* violation, the Sixth Circuit answered in the affirmative, and thereby functionally affirmed, a question that was certified for interlocutory appeal by the United States District Court for the Eastern District of Michigan.⁷

Rejecting the Sixth Circuit's holding in *Cardizem*, the United States Court of Appeals for the Eleventh Circuit ("Eleventh Circuit") reached a seemingly contrary conclusion in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*⁸ On September 15, 2003, the Eleventh Circuit held that two separate agreements between Abbott Laboratories, the manufacturer of a name-brand hypertension drug, and generic drug manufacturers Zurich Goldline and Geneva Pharmaceuticals, were not *per se* illegal even though the agreements involved payments to the generic manufacturers in exchange for their agreements not to enter the market.⁹ The Eleventh Circuit found that the district court had failed to consider the fact that, as a patent-owner, Abbott had a lawful right to exclude potential infringers from practicing its patents. On remand, the district court was instructed to analyze whether the agreements unlawfully exceeded this right.¹⁰

5. *Louisiana Wholesale Drug Co. (In re Cardizem CD Antitrust Litig.) v. Hoechst Marion Roussel, Inc.*, 332 F.3d 896 (6th Cir. 2003).

6. *Id.* at 899.

7. *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682 (E.D. Mich. 2000).

8. 344 F.3d 1294 (11th Cir. 2003).

9. *Id.* at 1310–11 ("[W]e do not think that a payment from the patentee to the alleged infringer should be automatically condemned under the antitrust laws, . . .") (footnote omitted).

10. *Id.* at 1311–12 ("[We do not] think that the evidence regarding the exit payments in this case allows a confident conclusion to be drawn at this stage of the litigation that the exclusionary effect of the Agreements were bolstered by the exit payments to a degree that exceeds the potential exclusionary power of the patent"; "The appropriate analysis on remand will likely require an identification of the protection afforded by the patents and the relevant law

In this casenote, Part II provides a brief background of the Hatch-Waxman Act. In Part III, the facts of the two cases are set out at greater length. Finally, in Part IV, we take a closer look at the faultline between patent and antitrust law and the apparent clash between the Sixth and Eleventh Circuits. We then suggest a framework for analyzing these types of cases in light of our view that both circuit courts may well have reached the correct conclusion, but via the wrong procedure.

II. THE HATCH-WAXMAN ACT

A company seeking to market a pharmaceutical drug in the United States must first obtain approval from the FDA.¹¹ Ordinarily, applications for FDA approval are filed as a new drug application ("NDA"), in which the applicant must provide test data sufficient to demonstrate that the drug is safe and effective.¹²

Prior to 1984, the NDA was the only method of obtaining FDA approval for a new drug, even for those who wished to make a generic version of an approved drug having identical active ingredients. This procedure was both time consuming and inefficient, and potentially exposed the applicant to a claim of patent infringement if the new drug was the subject of a patent.¹³ These hurdles made it difficult if not impossible for generic drug manufacturers to bring their products to market.

In an effort to eliminate these impediments to the introduction of generic drugs, Congress enacted the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (the "Hatch-Waxman Act"). The Hatch-Waxman Act authorized a company to obtain permission to market a generic version of an approved drug by filing an abbreviated new drug application ("ANDA"), which, among other things, allowed an ANDA applicant to rely on the safety and efficacy studies conducted for the pioneer drug.¹⁴ The Hatch-Waxman Act also modified the definition of infringement, so that the generic drug manufacturer's development activities are no longer considered to be infringing

and consideration of the extent to which the Agreements reflect a reasonable implementation of these."(Footnote omitted)).

11. See 21 U.S.C. § 355(a) (2003).

12. See § 355 (b)(1).

13. See 35 U.S.C. § 271(a) (2003).

14. See 21 U.S.C. § 355(j) (2003).

activity.¹⁵ Hatch-Waxman also allowed the extension of patent terms to compensate for the period when a patented drug could not be marketed because it was undergoing the FDA approval process.¹⁶

A key part of the Hatch-Waxman scheme centers on the FDA's "Orange Book."¹⁷ This resource contains patent information from manufacturers of pioneer drugs, along with other information about each listed drug. Specifically, NDA applicants are required to submit the patent number and expiration date of any patent that a generic manufacturer might infringe. If such a patent issues after approval of the NDA, the holder of the application is required to file the patent number and expiration date with the FDA no later than 30 days after the patent issues.¹⁸

The ANDA procedures require any company submitting an ANDA to make a certification with respect to each patent listed in the Orange Book that: (1) the patent information has not been filed with the FDA; (2) the patent is expired; (3) the patent will expire, identifying the expiration date; or (4) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug.¹⁹ If the ANDA applicant certifies that the relevant patents are invalid or will not be infringed (a "paragraph IV certification"), the applicant must provide notice to the patentee and the holder of the approved NDA that it has submitted such a certification.²⁰ If the patent holder brings suit for patent infringement within 45 days of receiving this notice, the FDA automatically delays approval of the ANDA for thirty months.²¹ This delay terminates automatically if the suit results in a finding of invalidity or non-infringement.²² Conversely, a finding of validity and infringement results in the setting of an approval date of the application for a date on or after the patent's expiration.²³

The Hatch-Waxman Act encourages generic manufacturers to challenge weak or narrow drug patents by providing an "exclusivity period" to the first company to file an ANDA. Competing generic drug manufacturers may sometimes file competing ANDAs that each include their own paragraph IV certification. Pursuant to the Hatch-

15. 35 U.S.C. § 271(e) (2003).

16. *See* § 156.

17. *See* 21 U.S.C. § 355(j)(7)(A) (2003).

18. *See* § 355(c)(2).

19. *See* § 355(j)(2)(A)(vii).

20. § 355(j)(2)(B)(i).

21. *See* § 355(j)(5)(B)(iii).

22. *See* § 355(j)(5)(B)(iii)(I).

23. *See* § 355(j)(5)(B)(iii)(II); 35 U.S.C. § 271(e)(4)(A) (2003).

Waxman Act, approval of an ANDA containing a paragraph IV certification is automatically delayed if another ANDA was previously filed based on the same listed drug and the previous ANDA contains a paragraph IV certification.²⁴ Approval of the subsequent ANDA is delayed until 180 days after the earlier of (1) the first commercial marketing of the drug under the previous application or (2) the date a court hearing an infringement action brought against the previous filer holds the patent invalid or not infringed.²⁵ This delaying mechanism gives the first generic manufacturer to file a paragraph IV certification and successfully challenge the scope or validity of a pioneer drug patent, a 180-day period during which it is the exclusive competitor of the pioneer manufacturer.

History has shown that there are some flaws in the Hatch-Waxman Act, the most notable of which is the potential misuse of the 180-day exclusivity period. Misuse can occur when, for example, a name-brand drug company pays a generic drug company that has filed an ANDA not to compete or to delay litigation in order to protect its dominant share of the market.²⁶ Such collusion can effectively "bottle-neck" the market for generic drug manufacturers who apply for an ANDA subsequent to the initial ANDA applicant. Recently, as evidenced by the cases described below, competitors and consumers have attempted to use the antitrust laws to address agreements that have effectively blocked generic drug manufacturers from the market.

III. FACTUAL BACKGROUND

A. In re: Cardizem CD Antitrust Litigation

On September 22, 1995, Andrx filed an ANDA with the FDA seeking approval to manufacture and sell a generic form of Cardizem CD.²⁷ The active ingredient in Cardizem CD is diltiazem hydrochloride, which is delivered to the user through a controlled-release system that requires only one dose per day.²⁸ Although HMR's patent for diltiazem hydrochloride expired in November of

24. See 21 U.S.C. § 355(j)(5)(B)(iv) (2003).

25. See § 355(j)(5)(B)(iv).

26. See Marcy L. Lobanoff, Comment, *Anti-Competitive Agreements Cloaked as "Settlements" Thwart the Purposes of the Hatch-Waxman Act*, 50 EMORY L.J. 1331, 1337-38 (2001).

27. Louisiana Wholesale Drug Co. (*In re Cardizem CD Antitrust Litig.*) v. Hoechst Marion Roussel, Inc., 332 F.3d 896, 902 (6th Cir. 2003).

28. *Id.* at 901.

1992,²⁹ HMR procured release-system patents to continue protecting its product. In November of 1995, the U.S.P.T.O issued U.S. Patent No. 5,470,584 (“‘584 patent”), which was licensed to HMR. The ‘584 patent claimed 0–45% of the total diltiazem in Cardizem CD would be released within 18 hours (‘584 patent is also referred to as the “45%–18 patent”).³⁰

On December 30, 1995, Andrx filed a paragraph IV certification stating that its generic product did not infringe any of the Cardizem CD patents listed in the Orange Book.³¹ Because Andrx was the first potential generic manufacturer of Cardizem CD to file an ANDA with a paragraph IV certification, it became entitled to the 180-day exclusivity period once it received FDA approval.³²

In January, 1996, HMR filed a patent infringement suit against Andrx in the United States District Court for the Southern District of Florida, asserting that the generic version of Cardizem CD that Andrx proposed would infringe the ‘584 patent.³³ While HMR’s complaint sought neither damages nor a preliminary injunction, the filing automatically triggered the 30-month waiting period during which the FDA could not approve Andrx’s ANDA and Andrx could not market its generic product.³⁴ In February of 1996, Andrx brought antitrust and unfair competition counterclaims against HMR.³⁵ In April, 1996, Andrx amended its ANDA to specify that the release profile for its generic product was *not* less than 55% of total diltiazem released within 18 hours (“55%–18 generic”).³⁶ Despite this amendment, HMR continued to pursue its patent infringement litigation against Andrx in defense of its 45%–18 patent.³⁷ On June 2, 1997, Andrx represented to the court that it intended to market its generic product as soon as it received FDA approval.³⁸

On September 15, 1997, the FDA tentatively approved Andrx’s ANDA, indicating that it would be granted final approval as soon as it was eligible, i.e., upon expiration of the thirty-month waiting period

29. *Id.*

30. *Id.* at 902.

31. *See id.*

32. *Id.*

33. *Louisiana Wholesale Drug*, 332 F.3d at 902.

34. *See id.*

35. *Id.*

36. *Id.*

37. *See id.*

38. *Id.*

in early July of 1998, or earlier, if the court in the patent infringement action ruled that the '584 patent was invalid or not infringed.³⁹

Nine days later, on September 24, 1997, HMR and Andrx entered into an agreement (the "Agreement") which provided that Andrx would not market any bioequivalent or generic version of Cardizem CD in the United States until the earliest of: (1) Andrx obtaining a favorable, final, and unappealable determination in the patent infringement case; (2) HMR and Andrx entering into a license agreement; or (3) HMR entering into a license agreement with a third party.⁴⁰ Andrx also agreed to dismiss its antitrust and unfair competition counterclaims, to diligently prosecute its ANDA, and to not "relinquish or otherwise compromise any right accruing thereunder or pertaining thereto," including its 180-day period of exclusivity.⁴¹ In exchange, HMR agreed to make interim payments to Andrx in the amount of \$40 million per year, payable quarterly, beginning on the date Andrx received final FDA approval.⁴² HMR further agreed to pay Andrx \$100 million per year,⁴³ less whatever interim payments had been made, once: (1) there was a final and unappealable determination that the patent was not infringed; (2) HMR dismissed the patent infringement case; or (3) there was a final and unappealable determination that did not determine the issues of the patent's validity, enforcement, or infringement, and HMR failed to re-file its patent infringement action.⁴⁴ HMR also agreed that it would not seek preliminary injunctive relief in the ongoing patent infringement litigation.⁴⁵

39. *Louisiana Wholesale Drug*, 332 F.3d at 902.

40. *Id.*

41. *Id.*

42. *Id.* The payments were scheduled to end on the earliest of: (1) a final and unappealable order or judgment in the patent infringement case; (2) if HMR notified Andrx that it intended to enter into a license agreement with a third party, the earlier of: (a) the expiration date of the required notice period or (b) the date Andrx effected its first commercial sale of the Andrx product; or (3) if Andrx exercised its option to acquire a license from HMR, the date the license agreement became effective. *Id.* at 902-03 n.3.

43. HMR and Andrx stipulated that, for the purposes of the Agreement, Andrx would have realized \$100 million per year in profits from the sale of its generic product after receiving FDA approval. *Id.* at 903 n.4.

44. *Louisiana Wholesale Drug*, 332 F.3d at 903. HMR had to notify Andrx within thirty days of such a determination that it continued to believe that Andrx's generic version of the drug infringed its patent and that it intended to refile its patent infringement action. *Id.* at n.5.

45. *Id.* at 903. HMR also agreed that it would give Andrx copies of changes it proposed to the FDA regarding Cardizem CD's package insert and immediate container label, that it would notify Andrx of any labeling changes pending before or approved by the FDA, and that it would grant Andrx an irrevocable option to acquire a nonexclusive license to all intellectual

On July 8, 1998, the statutory 30-month waiting period expired,⁴⁶ and on the next day, the FDA issued its final approval of Andrx's ANDA.⁴⁷ Pursuant to the Agreement, HMR began making quarterly payments of \$10 million to Andrx, and Andrx refrained from bringing its generic product to market.⁴⁸

On September 11, 1998, Andrx, filed a supplement to its previously filed ANDA, seeking approval for a reformulated generic version of Cardizem CD.⁴⁹ Andrx informed HMR that it had reformulated its product; it also urged HMR to reconsider its infringement claims.⁵⁰ On February 3, 1999, Andrx certified to HMR that its reformulated product did not infringe the '584 patent.⁵¹

On June 9, 1999, the FDA approved Andrx's reformulated product.⁵² That same day, HMR and Andrx entered into a stipulation settling the patent infringement case and terminating the Agreement.⁵³ At the time of settlement, HMR paid Andrx a final sum of \$50.7 million, bringing its total payments to \$89.83 million.⁵⁴ On June 23, 1999, Andrx began to market its product under the trademark Cartia XT, and its 180-day period of marketing exclusivity began to run.⁵⁵ Since its release, Cartia XT has sold for a much lower price than Cardizem CD and has captured a substantial portion of the market.⁵⁶

In August 1998, shortly after the FDA issued its final approval for Andrx's generic version of Cardizem CD, the first complaint regarding the Agreement was filed.⁵⁷ That complaint was consolidated with subsequent complaints for pretrial proceedings in the Eastern District of Michigan.⁵⁸

The crux of the matter for all plaintiffs was the allegation that but for the Agreement, specifically the payments of \$40 million per year, Andrx would have brought its generic product to market once it

property HMR owned or controlled that Andrx might need to market its product in the United States. *Id.* at n.6.

46. *Id.*

47. *Id.*

48. *Id.*

49. *Id.*

50. *Louisiana Wholesale Drug*, 332 F.3d at 903.

51. *Id.*

52. *Id.*

53. *Id.*

54. *Id.*

55. *Id.*

56. *Louisiana Wholesale Drug*, 332 F.3d at 903.

57. *Id.*

58. *Id.*

received FDA approval and at a lower price than the patented Cardizem CD sold by HMR.⁵⁹ The plaintiffs further alleged that the Agreement protected HMR from competition from both Andrx and other potential generic competitors because Andrx's delayed market entry postponed the start of its 180-day exclusivity period, which it had agreed not to relinquish or transfer,⁶⁰ thus, effectively locking the competition out of the market. The plaintiffs brought claims under various state antitrust laws as well as the federal antitrust laws, specifically Section 1 of the Sherman Act, 15 U.S.C. § 1. Additionally, the plaintiffs sought treble damages under section 4 of the Clayton Act, 15 U.S.C. § 15.⁶¹

HMR and Andrx filed various motions to dismiss.⁶² The district court denied them all.⁶³ Plaintiffs then moved for summary judgment on the issue of whether the Agreement was a *per se* illegal restraint of trade.⁶⁴ The district court held that the Agreement was *per se* illegal, specifically because HMR's payments to Andrx of \$10 million per quarter not to enter the market with its generic version of Cardizem CD were, according to the court, naked, horizontal restraints of trade.⁶⁵ The district court then certified the following question to the Sixth Circuit:

In determining whether Plaintiffs' motions for partial judgment were properly granted, whether the Defendants' September 24, 1997 Agreement constitutes a restraint of trade that is illegal *per se* under section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and under the corresponding state antitrust laws at issue in this litigation.⁶⁶

The Sixth Circuit responded:

Yes. The Agreement whereby HMR paid Andrx \$ 40 million per year not to enter the United States market for Cardizem CD and its generic equivalents is a horizontal market allocation agreement and, as such, is *per se* illegal under the Sherman Act and under the corresponding state antitrust laws. Accordingly, the district court

59. *Id.* at 904.

60. *Id.*

61. *Id.*

62. *Louisiana Wholesale Drug*, 332 F.3d at 903.

63. *Id.*

64. *Id.* at 905–06.

65. *Id.* at 906.

66. *Id.* at 900.

properly granted summary judgment for the plaintiffs on the issue of whether the Agreement was *per se* illegal.⁶⁷

B. Valley Drug Co. v. Geneva Pharmaceuticals, Inc.

In *Valley Drug*, the Eleventh Circuit reversed the district court's order granting summary judgment that two settlement agreements among the defendants constituted *per se* violations of § 1 of the Sherman Act, 15 U.S.C. § 1. At issue were separate agreements settling all or part of two separate pieces of litigation between three pharmaceutical companies; each settlement included payments from the patentee to the alleged infringer in exchange for agreements to delay entry into the market.

The litigation at issue in the two agreements arose out of patents related to the hypertension drug Hytrin.⁶⁸ Abbott Laboratories ("Abbott") was the owner of the patents and the manufacturer of the drug.⁶⁹ Abbott had obtained FDA approval of its NDA for Hytrin in 1987 and held a number of patents related to the active ingredient (terazosin hydrochloride) over the years.⁷⁰ Abbott's first patent, issued in 1977, covered the basic terazosin hydrochloride compound.⁷¹ Although that patent had expired, Abbott had obtained other patents for various crystalline forms of the compound and various methods of using and preparing the compound.⁷²

Geneva Pharmaceuticals, Inc. ("Geneva") filed four ANDAs based on Hytrin between 1993 and 1996, each time making paragraph IV certifications with respect to Abbott's patents.⁷³ In response, Abbott sued Geneva for infringement, which triggered the 30-month stay of FDA approval.⁷⁴ Thereafter, on April 29, 1996, Geneva filed two additional ANDAs with paragraph IV certifications based on Hytrin, one for a capsule form and one for a tablet form.⁷⁵ Within 45 days of receiving notice of Geneva's certifications, Abbott filed an infringement suit based on the tablet ANDA, asserting that Geneva's terazosin hydrochloride product in tablet form infringed Abbott's

67. *Id.*

68. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1296 (11th Cir. 2003).

69. *Id.* at 1298.

70. *Id.*

71. *Id.*

72. *Id.*

73. *Id.*

74. *Valley Drug*, 344 F.3d at 1298–99.

75. *Id.* at 1299.

patent number 5,504,207 ("the '207 patent").⁷⁶ In the suit, Geneva admitted infringement, but nonetheless contested the validity of the '207 patent. Abbott inadvertently failed to allege infringement based on the capsule ANDA, and thus, the FDA considered and approved the capsule ANDA in March 1998.⁷⁷ Once Abbott learned that Geneva's capsule had been approved, Abbott attempted to amend its complaint to allege that the capsule infringed the '207 patent.⁷⁸

Zenith Goldline Pharmaceuticals ("Zenith") filed an ANDA for a terazosin hydrochloride drug in June of 1994, making a paragraph IV certification with respect to Abbott's Hytrin patents.⁷⁹ Thereafter, Abbott was issued two additional patents related to Hytrin: on May 2, 1995, Abbott obtained U.S. Patent No. 5,412,095 (the "'095 patent"), and on April 2, 1996, Abbott obtained the '207 patent.⁸⁰ Instead of providing certifications with respect to the '095 and '207 patents, Zenith filed suit against Abbott, seeking to compel Abbott to remove the two patents from the Orange Book, which would eliminate Zenith's obligation to provide a certification. Additionally, Zenith sought a declaration that the patents were invalid and that its drug did not infringe the patents.⁸¹ Abbott counterclaimed for infringement. After the district court denied its motion for a preliminary injunction, Zenith filed an appeal with the United States Court of Appeals for the Federal Circuit.

These two pieces of litigation culminated in the two separate agreements referenced above. Abbott and Zenith entered into their agreement on March 31, 1998 ("the Zenith Agreement").⁸² The Zenith Agreement dismissed Zenith's claims seeking "de-listing" of Abbott's patents and Abbott's counterclaims for infringement.⁸³ As part of the agreement, Zenith made a number of significant admissions and promises. First, Zenith acknowledged the validity of each of Abbott's patents claiming terazosin hydrochloride and admitted that any terazosin hydrochloride product Zenith might market would infringe these patents.⁸⁴ Second, Zenith agreed not to sell or distribute any pharmaceutical product containing any form of

76. *Id.*

77. *Id.*

78. *Id.*

79. *Id.*

80. *Valley Drug*, 344 F.3d at 1299.

81. *Id.*

82. *Id.* at 1300.

83. *Id.*

84. *Id.*

terazosin hydrochloride until someone else introduced a generic terazosin hydrochloride product first or until Abbott's patent number 4,215,532 (the "'532 patent'") expired.⁸⁵ Finally, Zenith agreed not to sell or transfer its rights under any ANDA application relating to a terazosin hydrochloride drug, not to aid any other person in gaining FDA approval of a terazosin hydrochloride drug, and not to aid any other person in opposing or invalidating any of Abbott's patents claiming terazosin.⁸⁶ In exchange, Abbott agreed to pay Zenith \$3 million up front, \$3 million after three months, and \$6 million every three months thereafter until March 1, 2000, or until the Zenith Agreement terminated by its own terms.⁸⁷ Abbott also agreed not to sue Zenith for infringement if it entered the market consistent with the Agreement.⁸⁸

The next day, on April 1, 1998, Abbott entered into an agreement related to the Geneva litigation ("Geneva Agreement"). The Geneva Agreement did not resolve the litigation in its entirety. Instead, Geneva agreed not to sell or distribute any product containing any form of terazosin hydrochloride until either Abbott's '532 patent expired, someone else introduced a generic terazosin hydrochloride drug, or Geneva obtained a final, non-appealable judgment that its terazosin tablets and capsules did not infringe the '207 patent or that the patent was invalid.⁸⁹ Like Zurich, Geneva made agreements related to its ANDA and to other potential generic manufacturers. Specifically, Geneva agreed not to transfer or sell its rights under its ANDAs, including its right to the 180-day exclusivity period.⁹⁰ Geneva also agreed to oppose any subsequent ANDA applicant's attempt to seek approval of its application and to join and support any attempt by Abbott to seek an extension of the 30-month stay of FDA approval on Geneva's tablet ANDA.⁹¹ For its part, Abbott agreed to pay Geneva \$4.5 million each month until either someone else brought a generic terazosin hydrochloride product to market or Abbott won a favorable decision in the district court on its infringement claim.⁹² If Geneva won in district court, Abbott's \$4.5 million monthly payments would go into escrow pending resolution

85. *Id.*

86. *Valley Drug*, 344 F.3d at 1300.

87. *Id.*

88. *Id.*

89. *Id.*

90. *Id.*

91. *Id.*

92. *Valley Drug*, 344 F.3d at 1300.

of the appeal, with the escrowed funds going to the party prevailing on appeal.⁹³ Abbott reserved the right to terminate its payments after February 8, 2000, if no other generic terazosin hydrochloride product had been marketed as of that date.⁹⁴ If Abbott exercised this right, it would execute a release in Geneva's favor of any claims of infringement based on the '207 patent.⁹⁵

Various class action and individual antitrust lawsuits were filed against Abbott, Zenith, and Geneva.⁹⁶ Those actions were consolidated by the Judicial Panel on Multidistrict Litigation in the Southern District of Florida. In response to the plaintiffs' joint motion for summary judgment, the district court focused on the defendants' agreements not to enter the market. The district court found that the agreements were "geographic market allocation Agreements between horizontal competitors, essentially allocating the entire United States market for terazosin drugs to Abbott" and thus *per se* violations of Section 1 of the Sherman Act.⁹⁷

Following the grant of summary judgment, Zenith entered into a tentative settlement, and Abbott and Geneva were granted permission to take an interlocutory appeal.⁹⁸ In reversing the district court's ruling, the Eleventh Circuit concluded that the agreements were not *per se* illegal because Abbott was lawfully entitled to use its patents to exclude competitors from the market.⁹⁹ However the Eleventh Circuit did not find that the agreements were actually legal:

It may be that the size of the payment to refrain from competing, sometimes called a "reverse payment" or an "exit payment," raises the suspicion that the parties lacked faith in the validity of the patent, particularly when those payments are non-refundable in the event that the patentee prevails on the infringement claim (as a bond posted as part of a preliminary injunction would be). However, in the instant case and given the state of the current

93. *Id.*

94. *Id.* at 1300–01.

95. *Id.* at 1301. (The court subsequently held the '207 patent invalid because the crystalline form of terazosin hydrochloride claimed in the patent was on sale in the United States more than one year before Abbott applied for the patent. The decision was affirmed by the Federal Circuit and Abbott's petition for certiorari was denied).

96. *Id.* at 1295–96.

97. *Id.* at 1301.

98. *Valley Drug*, 344 F.3d at 1296 n.1.

99. *Id.* at 1311.

record, it is difficult to infer from the size of the payments alone that the infringement suits lacked merit.¹⁰⁰

The Eleventh Circuit thus remanded the case for further proceedings.

IV. THE FAULTLINE: QUESTIONABLY COMPETITIVE SETTLEMENTS OF PATENT CASES

The seeming clash between the Sixth and Eleventh Circuits reveals the faultline between patent and antitrust law when antitrust claims are brought in response to pharmaceutical patent settlement agreements related to Hatch-Waxman considerations. It has been said that the patent and antitrust regimes are in place to support competition and the consumer while fostering innovation, but they do so in ways that sometimes meet up like tectonic plates colliding. Patent law gives inventors a marketplace monopoly for 20 years, which is an incentive to inspire competition, innovation, and choice.¹⁰¹ Antitrust law ensures that corporations do not act in improperly monopolistic ways or make "certain agreements tending to restrict output and elevate prices and profits above the competitive level."¹⁰² As a result of a patent grant, a patentee is entitled to engage in actions that, notwithstanding the patent grant, would be considered illegal under antitrust law.¹⁰³ However, a patent does not absolve the owner of potential liability under the antitrust laws, and it is when the patentee "overachieves" in a settlement that the legal analysis is most complicated.¹⁰⁴ And it is here that the Sixth and Eleventh Circuits clashed on the questions of when a patentee oversteps her patent monopoly, and how such cases should be analyzed.

The main points of disagreement between the Sixth and Eleventh circuits are whether the agreements at issue are *per se* illegal under the antitrust laws, and how such agreements should be analyzed. The Sixth Circuit believes that such agreements are *per se* illegal, while the Eleventh Circuit believes that the extent of the patent grant must

100. *Id.* at 1309–10.

101. See 35 U.S.C. § 154(a)(2); AREEDA, HOVENKAMP & ELHAUGE, *supra* note 5, ¶ 1780a, at 471 ("Patent law . . . serves the interests of consumers by protecting invention against prompt imitation in order to encourage more innovation than would otherwise occur.").

102. AREEDA, HOVENKAMP & ELHAUGE, *supra* note 5, ¶ 1780a, at 470–71.

103. See Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1725–30 (2003) (discussing examples of antitrust exceptions for patents).

104. See *id.* at 1739–65 (detailing various patent settlement provisions from least to most problematic under antitrust laws).

be analyzed before any decision on the antitrust claim can be made. As the discussion below demonstrates, because the terms of the settlement agreements differ slightly, albeit crucially, both courts came to defensible conclusions. Yet, the divergent process that each court took to come to its decision is problematic; we believe there is a better way.

The Sixth Circuit's approach is too blunt and could well result in a finding that valid settlement agreements are illegal *per se* antitrust violations, which would unfairly penalize good faith attempts to amicably settle a dispute. The Eleventh Circuit's approach, on the other hand, is inefficient and unnecessarily punishing to valid antitrust plaintiffs. Under the Eleventh Circuit's approach, the settlement agreement must be measured against the patent grant. Although offering no clear guidance on how this is to be accomplished, the Eleventh Circuit's rule would, as a matter of logic, require the district court to first determine the scope of the right to exclude, presumably through extensive discovery, expert analysis, and claim construction.¹⁰⁵ This course thus pushes every agreement into a complex, time-consuming, and extremely costly analysis of the patent grant; essentially a district court would have to conduct an entire patent infringement and invalidity trial before even reaching the substantive antitrust issues. By starting with the power of the patent grant, the Eleventh Circuit recommends a process for resolving such disputes that may be unnecessarily complicated.

We believe that in cases involving exclusion payments from the patent owner to the accused infringer, the proper analysis first addresses the following threshold questions: first, whether the payments exceed the expected litigation costs of the patent owner¹⁰⁶ and, second, whether the exclusion agreement—the promise given as consideration for the exclusion payment—facially exceeds the patent grant, i.e., exceeds the relief that the patent owner could have obtained from a reviewing court. Where payments exceed the litigations costs or where the exclusion agreement facially exceeds the patent grant, the agreement would be *per se* illegal.

105. See, e.g., *Valley Drug*, 344 F.3d at 1312 (“The appropriate analysis on remand will likely require an identification of the protection afforded by the patents and the relevant law and consideration of the extent to which the Agreements reflect a reasonable implementation of these.”)(Footnote omitted)).

106. See Hovenkamp, *supra* note 104, at 1759–60 (suggesting that any payment from a patentee to an infringement defendant should be presumptively unlawful).

A. *The Sixth Circuit's View.*

In the *Cardizem* case, the Sixth Circuit held that the settlement agreement before it was a "naked, horizontal restraint" and was *per se* illegal under Section 1 of the Sherman Act.¹⁰⁷ While acknowledging that most restraints are evaluated under the "rule of reason," the Sixth Circuit held that the Agreement was unreasonable *per se* because it was "at its core, a horizontal restraint agreement to eliminate competition in the market for Cardizem CD throughout the United States[.]"¹⁰⁸ While a defensible conclusion, the Sixth Circuit's analysis focused on facts¹⁰⁹ that, if followed by other courts, may lead to an overinclusive *per se* rule. However, the existence of two other facts is more relevant to the analysis. First, the \$40 million per year exclusion payments far exceeded any reasonable expectation of the patentee's litigation costs. Second, the exclusion agreement by the accused infringer facially exceeded the scope of the patent grant. Central to the district court's decision had been the fact that the settlement agreement "restrained Andrx from marketing other bioequivalent or generic versions of Cardizem CD which were not at issue in the pending . . . patent case" and thus not only delayed Andrx's entry into the market, but also delayed the entry of Andrx and all other generic competitors who may have *non-infringing* generic drugs.¹¹⁰ This concern was highlighted by the Sixth Circuit in its analysis of antitrust injury,¹¹¹ but it is unclear from the decision how much weight the fact that the Agreement blocked non-infringing products had on the court's decision to use the *per se* rule. Thus, the opinion is sufficiently ambiguous to allow a lower court to hold a similar agreement that did not block non-infringing products as *per se* illegal, which may be an unwarranted result after a more appropriate, and searching, review.

While the determination that this particular agreement was *per se* illegal is a defensible conclusion, by painting all such agreements with such a broad brush the Sixth Circuit may well invalidate agreements that are legal under the patent laws and not anticompetitive. For example, if a generic drug plaintiff conceded

107. "Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal . . ." 15 U.S.C. § 1.

108. *Louisiana Wholesale Drug Co. (In re Cardizem CD Antitrust Litig.) v. Hoechst Marion Roussel, Inc.*, 332 F.3d 896, 906-08 (6th Cir. 2003).

109. *Id.* at 907-08.

110. *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682, 697 (E.D. Mich. 2000).

111. *Louisiana Wholesale Drug*, 332 F.3d at 910.

infringement but argued that the pioneer drug patent was invalid, it is unlikely the generic drug company would risk infringement and willfulness damages by producing the generic drug upon expiration of the thirty-month delay under Hatch-Waxman. Moreover, where the agreement specifically only covered the product at issue, it is difficult to imagine why such an agreement should run afoul of antitrust. However, under the broad language of the *Cardizem* court, it would likely be *per se* illegal. In sum, the Sixth Circuit may well have reached the right result concerning this particular agreement, but via the wrong process.

B. The Eleventh Circuit's Perspective.

In *Valley Drug*, the Eleventh Circuit did not dispute the general and long-standing principle that “[a]n agreement between competitors to allocate markets is . . . clearly anticompetitive.”¹¹² As the court noted, such agreements have an “obvious tendency to diminish output and raise prices.”¹¹³ This reason is sufficient to find such agreements illegal *per se*, thereby obligating the courts to do little more than examine “the agreement itself and the relationships of the parties to the agreement.”¹¹⁴ However, the Court also noted that this approach is not appropriate in every case, such as those involving patents: “[i]f this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the district court’s order. This is not such a case, however, because one of the parties owned a patent.”¹¹⁵

The Eleventh Circuit emphasized that the patent is itself a grant to the owner providing a lawful right to exclude others.¹¹⁶ Thus, while a patentee’s right to exclude is not unfettered, the mere fact that an agreement results in exclusion does not end the inquiry into whether the agreement is illegal under the antitrust laws. The Eleventh Circuit criticized the district court for failing to take into account Abbott’s lawful right to exclude.¹¹⁷ The Eleventh Circuit

112. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1304 (11th Cir. 2003).

113. *Id.*

114. *Id.* at 1303.

115. *Id.* at 1304 (emphasis added).

116. *Id.* at 1304.

117. *Id.* at 1305 (“In characterizing the Agreements as territorial market allocation agreements, the district court did not consider that the ‘207 patent gave Abbott the right to exclude others from making, using, or selling [the active ingredient] until October of 2014, when it is due to expire.”).

found that the exclusionary effects of the two agreements were "at the heart of the patent right and *cannot* trigger the *per se* label."¹¹⁸

In reaching its conclusion, the Eleventh Circuit considered the Sixth Circuit's holding in *Cardizem*, but found that the Sixth Circuit had failed to consider in its analysis the patent-owner's lawful right to exclude.¹¹⁹ The Eleventh Circuit also relied on facts that were not present in *Cardizem*, such as the fact that the *Cardizem* Agreement contained language that arguably restricted noninfringing products.¹²⁰ The *Valley Drug* court found that, failing to apply the proper analysis and with apparently different facts, the *Cardizem* decision was not persuasive.¹²¹

While correctly not condemning the agreement before it as *per se* illegal, the Eleventh Circuit turned too quickly to a determination that settlement agreements must be first evaluated under the patent laws. Moreover, the Eleventh Circuit failed to provide any guidance as to how these rights could be measured, leaving the district court with no choice but to follow the guidance of *Markman v. Westview Instruments, Inc.*,¹²² and its progeny. The Eleventh Circuit's conclusion thus results in judicial inefficiency by failing to provide a means for eliminating cases involving agreements that are clearly within the patent grant.

C. *An Alternative Framework For Evaluating Cases.*

While the two circuits approached the question from two different directions, the final determinations by the courts of the agreements before them are not necessarily at odds. That is, in the end, the agreement before the Sixth Circuit may rightly be subjected to an abbreviated analysis, and the agreement before the Eleventh may well need a more searching treatment. The fault of both courts was the way in which they arrived at their respective conclusions; the Sixth's may sweep too broadly, while the Eleventh's may be inefficient. We believe an appropriate alternative approach is a modification of the general framework advocated by Professor

118. *Valley Drug*, 344 F.3d at 1306 (emphasis added).

119. *Id.* at 1310-11.

120. *Id.* at 1311 n.26.

121. *Id.*

122. 517 U.S. 370 (1996).

Hovenkamp and his colleagues for cases involving antitrust challenges to patent settlement agreements.¹²³

Under this alternative analysis, payments from a patentee to an accused infringer would not be *per se* illegal (as the Sixth Circuit believes) nor would they require searching patent analysis (as the Eleventh Circuit believes) nor would they be presumptively illegal (as Professor Hovenkamp advocated). Instead, a reviewing court should first ask two questions: (1) whether the exclusionary component of the settlement agreement (i.e., the exclusionary payment and corresponding agreement) is excessive because the payment exceeds the reasonably anticipated litigation costs of the patentee; and (2) whether the agreement to refrain from entering into a market facially exceeds the scope of the patent grant, either temporally or substantively. If the answer to either question is affirmative, the agreement would be *per se* illegal, and the case would proceed accordingly. If, however, the answer to both of these questions is in the negative, the antitrust challenge must fail. It is only in other circumstances, such as where a generic drug manufacturer asserts only invalidity or where it is not facially evident whether an agreement exceeds the scope of the patent grant, that a more searching analysis under the patent laws would be required.

V. CONCLUSION

When a patent settlement agreement under Hatch-Waxman is brought to the courts for scrutiny under the antitrust laws, a faultline between the patent and antitrust regimes becomes apparent in the collision between these regimes. Here, the Sixth Circuit's opinion in *In re: Cardizem CD Antitrust Litigation* and the Eleventh Circuit's opinion in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.* demonstrate how courts are struggling to resolve the application of antitrust law to pharmaceutical patent settlements under Hatch-Waxman. While both courts may well have reached appropriate conclusions, each employed procedures at odds with the other, and moreover, these approaches have the potential to produce overreaching or inefficient decisions in downstream courts. Adopting the framework described in this casenote, however, will provide greater stability and efficiency to the faultline where patent and antitrust collide in these types of pharmaceutical patent settlement agreements.

123. See Hovenkamp, *supra* note 104, at 1756–60 (suggesting rule for Hatch-Waxman cases).

